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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,093	12/06/2004	Frank Seibertz	RO0953US(#90568)	1122

7590
D Peter Hochberg
Baker Building
6th Floor
1940 East 6th Street
Cleveland, OH 44114

EXAMINER

ROBERTS, LEZAH

ART UNIT	PAPER NUMBER
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1612

MAIL DATE	DELIVERY MODE
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05/11/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,093	Applicant(s) SEIBERTZ ET AL.	
	Examiner LEZAH W. ROBERTS	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-90 is/are pending in the application.
- 4a) Of the above claim(s) 7-10, 24-41 and 47-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 11-23, 42-46 and 83-90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims

Claims 1-6, 11-23 and 42-46 are rejected under 35 U.S.C. 102(b) as being anticipated by McGinity et al. (US 2001/0006677).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 11-23, 42-46 and 83-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGinity et al. (US 2001/0006677) in view of Zerbe et al. (US 6,177,096).

McGinity et al. disclose effervescent polymeric film drug delivery systems that are adapted for direct oral or buccal administration. The formulations provide for a rapid rate of release of an active ingredient that ranges from immediate to a period of about 10 minutes (paragraph 0016) encompassing claim 13. The films may be single layer or multilayer films. The films comprise a water soluble or swellable film binder, and active ingredient, a plasticizer and an effervescent couple (paragraph 0016). The binders include acacia, tragacanth, gelatin, starch, cellulose materials such as methyl cellulose and sodium carboxymethyl cellulose, alginic acids and salts thereof, polyethylene glycol, guar gum, polysaccharide, sugars, invert sugars, poloxomers, collagen, albumin, gelatin, cellulose in nonaqueous solvents, and combinations of the above and the like. Other binders include, for example, polypropylene glycol, polyoxyethylene-polypropylene copolymer, polyethylene ester, polyethylene sorbitan ester, polyethylene oxide or combinations thereof and the like (paragraph 0082), encompassing claims 83, 85-87, 89 and 90. The effervescent couple produces a gas, such as carbon dioxide or oxygen, when in water (paragraph 0032). Effervescent components include sodium bicarbonate and sodium carbonate (paragraph 0076) and acids such as citric acid and maleic acid (paragraph 0073). The film will dissolve/disintegrate at a controlled rate when exposed to a water containing solution. The thickness of the film ranges from 0.1 mm to 2 mm (paragraph 0033) encompassing claims 18, 45 and 46. As a single layer, the film will be the product of a single extrusion. When a multi-layered film is involved, the different layers can be co-extruded in an extruder equipped with two die slots and then laminated together; alternatively, the different layers can be separately extruded

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one on the other (paragraph 0045). Flavorings include peppermint oil, which comprises menthol¹. The components are mixed together, encompassing suspending the components in a suspending agent as recited in the instant claims (paragraph 0094). The compositions may also comprise non aqueous solvents for the film forming polymer (paragraph 0082). Hot-melt extrusion processes in the art have generally required extremely elevated temperatures, which could degrade extruded materials such as those that combine to form an effervescent composition. A need continues to exist in the art for improved effervescent film preparations useful in a hot-melt extrusion process (paragraph 0015).

The reference differs from the instant claims insofar as it does not disclose the coating compound composition is dried.

Zerbe et al. disclose water soluble film for oral administration with instant wettability. The film is coated and dried utilizing existing coating technology and exhibits instant wettability followed by rapid dissolution/disintegration upon administration in the oral cavity (col. 1, lines 13-16). The compositions comprise polymers such as hydroxypropylmethyl cellulose, hydroxyethyl cellulose, or hydroxypropyl cellulose, either alone, or mixtures thereof as well as polyvinyl pyrrolidone, carboxymethyl cellulose, polyvinyl alcohol, sodium alginate, polyethylene glycol, natural gums like xanthane gum, tragacantha, guar gum, acacia gum, arabic gum and water-dispersible polyacrylates (col. 2, lines 37-51), encompassing claims 83-90. The compositions are made by dissolving the components into a compatible solvent, followed by casting the film and

¹ Blackwell et al., US 4,440,790, disclose peppermint comprises menthol (col. 1, lines 12-18).

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drying the film. The compositions may also comprise flavor enhancing agents such as citric acid and tartaric acid (col. 3, lines 38-40). The thickness of the resulting film depends on the concentration of solids in the coating solution and on the gap of the coating head and can vary between 5 and 200 μm . In order to reliably avoid an adverse feeling in the mouth, a dry film thickness of 70 μm should not be exceeded.

The reference differs from the instant claims insofar as it does not disclose at least one or two gas forming agents.

When using a non aqueous solvent in the process for making the compositions of McGinity et al. it would have been obvious to have dried the film to remove the solvent motivated the desire to form a dry film, as disclosed by Zerbe et al.

It would also have been obvious to use a non aqueous solvent to dissolve the components of the film composition, cast the films and dry them to make the compositions of McGinity et al. motivated by the desire to avoid high temperatures that may degrade the effervescent components by using a method disclosed in the art that is used to make water dispersible films with a compatible solvent.

In regard to claims 84 and 88, generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have used an acrylate polymer in the composition McGinity et al. motivated by the desire to use a water-dispersible polyacrylate for its function as a binding agent in a water dispersible film.

Claims 1-6, 11-23, 42-46 and 83-90 are rejected.

Claims 7-10, 24-41 and 47-82 are withdrawn.

No claims allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612